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April 9, 1999

Dockets Management Branch (HFA 305)
The U.S. Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20852

Re : Docket Number 98P-0504

To Whom This May Concern,

I am writing this letter to you concerning the petition filed by the Center for Science in the Public Interest that asks that the USFDA to require non-detectable levels of Vibrio vulnificus in oysters by way of a post- harvest treatment process for all oysters. Our company is strongly opposed to such an action.

By way of history, P & J Oyster Company, Inc. is one of the oldest oyster processing and distributing companies in the United States. Having opened for business in 1876 by my cousins and their partners, P & J has to our knowledge, been implicated in only one oyster illness case. Having such an outstanding record as ours, I believe that any requirement to post-harvest treat oysters would be an infringement on my rights as a successful business. I am not a scientist, but with a record such as ours, we must have been following the National Shellfish Sanitation Program properly.

The following are our company's answers to the questions posed by the USFDA in the Federal Register:

1. No, the Ameripure process is not readily employable and barriers exist to implement a requirement to reduce V.v. bacteria to non-detectable levels. First, the Ameripure oyster is not readily accepted in the marketplace. Second, the cost to obtain a license to sell Ameripure oysters is quite expensive for a product that is not proven to be accepted in the market, nor shown to be profitable. The steps that can be taken to reduce and/or eliminate those barriers are for the Ameripure Company, USFDA, or any other agency to obtain unsecured loans for all processors currently processing and handling Gulf oysters. The loans would be used to build facilities, capable to process oysters with the Ameripure process. They would also have to guarantee the Ameripure oysters acceptance in the marketplace, as well as, a guarantee that the processors will be profitable.

2. As of today, there are two PHT's which will reduce Vibrio vulnificus levels in shellfish to non-detect levels, the Ameripure process and individual quick freezing with carbon dioxide. Future PHT's which are anticipated are high pressure processing and irradiation. The GOIC supports the development of PHT's for shellfish, but also believes that every consumer should be allowed to make an educated decision when they choose to eat any food, including raw oysters. Since Vibrio vulnificus is not "ordinarily injurious" to the general population, requiring that all certified shellfish dealers process oysters to reduce Vibrio vulnificus levels in shellfish to a non-detectable level would be an overly burdensome regulation. The GOIC opposes any regulation that would require oysters to be PHT.

3. No, there is no technology available today that has proven to be accepted by consumers across the nation. Profitability is also a concern. The current PHT's have been found to have downsides that may be problematic to the processor's ability to make a profit. For the IQF process, there is an overabundance of cut, or standard oysters left over after freezing the best oysters on the half shell. As for the Ameripure processed oyster, there seems to be a problem with returns and oysters that loose the sensory qualities necessary to sell them on the half shell.

98P-0504

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OYSTER PROCESSOR
AND DISTRIBUTOR

4. Setting a performance standard of non-detectable for V.v. in oysters is unnecessary for a number of reasons. First, V.v. is not an ordinarily injurious bacterium, and can be ingested by most people without any harmful effects. We should never set performance standards for any food, so that the immune compromised person will be guaranteed ill effect. That is insurmountable position to take. Secondly, the infective dose of V.v. is unknown. Requiring a performance standard without the infective dose of V.v. known and confirmed by the scientific community is over burdensome and uncompromising.

5. If a performance standard is required for oysters, which I do not believe that it should, the standard should be required for all molluscan shellfish.

6. The quantifiable, as well as nonquantifiable costs of requiring a performance standard will be very hard to determine. The following are some costs that may impact the shellfish industry.

The quantifiable startup costs may be:

a. Buy a license to use and operate a PHT
b. Buy and build a facility and equipment
c. Relocation of the processing facility
d. Increased handling costs

The nonquantifiable costs may be:

a. The cultural loss from the recreational harvester, to the farmer/fisherman, to the processor, and to the consumer.
b. The loss of the nutritional value of an all natural, unprocessed raw oyster product.

7. The quantifiable and unquantifiable benefits of a performance standard for oysters and who will enjoy those benefits are quite limited. There are only a small number of people who are in the at-risk group that may become ill from eating oysters that contain Vibrio vulnificus. There are nearly 600,000 Louisiana oysters consumed daily, much less counting all the other oysters eaten raw from the other Gulf States. Having said that, the fact is that very few people will receive any benefit from having to eat post-harvest treated oysters that meet a performance standard of non-detectable for Vibrio vulnificus. There is also no guarantee that the USFDA, CSPI, State shellfish control agencies or any processor can give to an at-risk consumer that a post-harvest treated oyster will not cause any concern whatsoever, if they may choose to eat the oysters not fully cooked.

In closing, I would like to express that our company knows that the requirements called for by the CSPI petition to require a performance standard of non-detectable levels of Vibrio vulnificus is unattainable and could never be guaranteed by anyone. Neither a regulatory agency nor anyone in the shellfish industry could make such a guarantee. And you can mark my word that anyone who does make such a guarantee, does not understand what the effects of cross-contamination can do to any food throughout the distribution chain.

Sincerely,

Alfred R. Sunseri
President
P & J Oyster Company, Inc.

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